

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|--------------|---------------------------------------|-----------------------|
| Appl. No.    | : 10/560,508                          | Confirmation No. 5660 |
| Applicant:   | : Sajinder Kaur Luthra, <i>et al.</i> |                       |
| Filed        | : January 29, 2007                    |                       |
| TC/A.U.      | : 1618                                |                       |
| Examiner:    | : Dameron Levest Jones                |                       |
| Docket No.   | : PH0423                              |                       |
| Customer No. | : 36335                               |                       |

Commissioner for Patents  
P.O. Box 1450  
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**AMENDMENT**

Sir:

In response to the Office Action of August 25, 2011, please amend the above-identified application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks/Arguments** begin on page 7 of this paper.

### Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

#### Listing of Claims:

Claims 1-13 (Canceled).

14. (Currently Amended) A process for purifying a radiolabelled product comprising the steps of:

(i) reacting a precursor with a radioisotope or radiolabeling agent to form a solution-phase radiosynthesis reaction mixture comprising a radiolabelled product and excess precursor;

(ii) contacting said solution-phase radiosynthesis reaction mixture with a solid-support bound scavenger group of formula (IV):



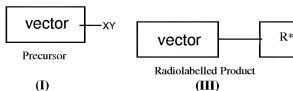
wherein:

Z is a scavenger group selected from the group consisting of: isocyanate, isothiocyanate, thiol, hydrazine, hydrazide, aminooxy, 1,3-dipole, aldehyde, ketone,  $-\text{NH}_2$ ,  $\text{H}_2\text{N}-\text{C}_{1-15}\text{alkyl}$ ,  $\text{H}_2\text{N}-\text{C}_{7-15}\text{aryl}$ ,  $\text{H}_2\text{N}-\text{NH}-$ ,  $\text{H}_2\text{N}-\text{NH}-\text{C}(=\text{O})$ ,  $\text{H}_2\text{N}-\text{O}-$ , phenylhydrazines, semicarbazide, and thiosemicarbazide; and

SP is a solid support;

wherein said excess precursor forms a covalent bond with said solid-phase support bound scavenger group compound of formula (IV); and

(iii) separating said radiolabelled product in the solution-phase; and wherein .  
said excess precursor is of formula (I) and said radiolabelled product is of formula (III):



wherein XY is either a leaving group capable of reacting with said radioisotope or said radiolabeling agent or a functional group which can react site-specifically with a moiety on said radiolabeling agent~~a functional group~~ and R\* is a radioisotope or radiolabelled moiety~~portion~~.

15. (Cancelled).

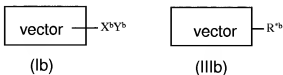
16. (Previously presented) The process according to claim 14 wherein said excess precursor is of formula (Ia) and said radiolabelled product is of formula (IIIa):



wherein R<sup>1</sup> is C<sub>1-6</sub> alkyl and R\* is [<sup>11</sup>C]-C<sub>1-6</sub>alkyl, [<sup>18</sup>F]fluoro C<sub>1-6</sub> alkyl or [<sup>18</sup>F]fluoro C<sub>6-12</sub> aryl;

and Z of the compound of formula (IV) is isocyanate or isothiocyanate.

17. (Previously presented) The process according to claim 14 wherein said excess precursor is of formula (Ib) and said radiolabelled product is of formula (IIIb):



wherein either

(i) the functional group —X<sup>b</sup>Y<sup>b</sup> in the compound of formula (Ib) is —OSO<sub>2</sub>R<sup>3</sup> wherein R<sup>3</sup> is C<sub>1-15</sub> alkyl or C<sub>1-10</sub> alkylaryl and R<sup>3</sup> is optionally substituted by halo and R<sup>b</sup> in the compound of formula (IIIb) is a radiohalogen; or

(ii) the functional group  $-X^bY^b$  in the compound of formula (Ib) is  $-C(O)CH_2Cl$  and  $R^b$  in the compound of formula (IIIb) is  $-S-L^b-^{18}F$  wherein  $L^b$  is a  $C_{1-30}$  hydrocarbyl linker group optionally including 1 to 10 heteroatoms; and  $^{18}F$  is a radioisotope of fluorine; and

Z of the compound of formula (IV) is thiol.

18. (Previously presented) The process according to claim 14 wherein said excess precursor is of formula (Ic) and said radiolabelled product is of formula (IIIc):



wherein the functional group  $-X^cY^c$  in the compound of formula (Ic) is an aldehyde or ketone and  $R^{*c}$  in the compound of formula (IIIc) is  $=N-W-Linker-F$  where W is  $C_{1-15}$  alkyl or  $C_{7-15}$  aryl; and

Z of the compound of formula (IV) is  $-NH_2$ , hydrazine, hydrazide, aminoxy, phenylhydrazines, semicarbazide, or thiosemicarbazide.

19. (Previously presented) The process according to claim 14 wherein said excess precursor is of formula (Ic) and said radiolabelled product is of formula (IIIc):



wherein the functional group  $-X^cY^c$  in the compound of formula (Ic) is  $-\text{OSO}_2\text{R}^3$  wherein  $\text{R}^3$  is  $\text{C}_{1-15}$  alkyl or  $\text{C}_{1-10}$  alkylaryl and  $\text{R}^3$  is optionally substituted by halo and  $\text{R}^{*c}$  in the compound of formula (IIc) is  $=\text{N-W-Linker-F}$  where W is  $\text{C}_{1-15}$  alkyl or  $\text{C}_{7-15}$  aryl; and

Z of the compound of formula (IV) is  $\text{H}_2\text{N-C}_{1-15}\text{alkyl}$ ,  $\text{H}_2\text{N-C}_{7-15}\text{aryl}$ ,  $\text{H}_2\text{N-NH-}$ ,  $\text{H}_2\text{N-NH-C(=O)-}$ , or  $\text{H}_2\text{N-O-}$ .

20. (Previously presented) The process according to claim 14 wherein said excess precursor is of formula (Id) and said radiolabelled product is of formula (IIId):



wherein the functional group  $-\text{X}^d\text{Y}^d$  in the compound of formula (Id) is an amine, hydrazine, hydrazide, aminoxy, phenylhydrazine, semicarbazide, or thiosemicarbazide group and  $\text{R}^{*d}$  in the compound of formula (IIId) is  $=\text{CH-Linker-[18F]F}$  where the linker comprises an alkyl, aryl or polyethylene glycol component; and

Z of the compound of formula (IV) is an aldehyde or ketone.

21. (Previously presented) The process according to claim 20 wherein Z is a ketone based on a ring-opening metathesis polymerisation (ROMP) polymer backbone.

22. (Cancelled).

23. (Cancelled).

## **REMARKS/ARGUMENTS**

### **I. Amendment to the Claims**

Claim 14 has been amended to clarify Applicants' claimed invention. Specifically Claim 14 has been amended to recite:

- (i) at line 17, "said solid-support bound scavenger group of Formula (IV)";
- (ii) "XY" as "either a leaving group capable of reacting with said radioisotope or said radiolabeling agent or a functional group which can react site-specifically with a moiety on said radiolabeling agent"; and
- (iii) "R\*" as "a radioisotope or radiolabelled moiety".

Support for amendments:

- (i) can be found in claim 14, lines 6-7;
- (ii) can be found on page 4, lns. 9-14 of the Specification; and
- (iii) can be found, for example, on page 7, lns. 9-15 and page 9, lns. 3-6 of the Specification.

No new matter has been added. Solely to expedite prosecution, Claims 22 and 23 have been cancelled without waiver or prejudice. Upon entry of the present amendment, Claims 14 and 16-21 will be pending.

### **II. Rejection Under 35 U.S.C 112, First Paragraph**

Claims 14-23 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been rendered moot by the present amendment to the claims. Applicants respectfully request this rejection be withdrawn.

### **III. Rejection Under 35 U.S.C 112, Second Paragraph**

Claims 14 and 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention. This rejection has, in part, been rendered moot by the present amendment to the claims and, in part, respectfully traversed.

(a) Claims 14 and 16-23 are ambiguous as written because it is unclear what “functional group” and “radiolabeled portion” Applicant is referring to in Formula I. This rejection has been rendered moot by the present amendment to claim 14. Applicants respectfully request this rejection to be withdrawn.

(b) Claim 14: there is insufficient antecedent basis for the limitation of “said compound” at line 17. This rejection has been rendered moot by the present amendment to claim 14. Applicants respectfully request this rejection to be withdrawn.

(c) Claims 22 and 23: there is insufficient antecedent basis for the limitation “said reaction by-product” in lines 1-2 and 5 of claim 22 and line 2 of claim 23. This rejection has been rendered moot by the present cancellation of claims 22 and 23. Applicants respectfully request this rejection to be withdrawn.

#### **IV. Conclusion**

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner’s rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Appl. No. 10/560,508  
Amdt. Dated November 22, 2011  
Reply to Office action of August 25, 2011

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.16(j) or 37 CFR 1.136(a) which may be required, or credit any overpayment, to Deposit Account No. 502-665 in the name of GE Healthcare, Inc.

Respectfully submitted,

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